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OCT 2 7 2011

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510(k) Summary

TurboHawk® Peripheral Plaque Excision System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.

1. Submitter Information

Applicant	ev3 Inc. 3033 Campus Drive Plymouth, MN 55441-2651 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Brenda Johnson Principal Regulatory Affairs Specialist
Date Prepared	October 7, 2011

2. Subject Device

Device Trade Name	TurboHawk® Peripheral Plaque Excision System
Device Common Name	Catheter, Peripheral, Atherectomy
Classification Name	Intraluminal Artery Stripper 21 CFR 870.4875, Product Code MCW
Classification Panel	Cardiovascular

3. Predicate Devices

Device Trade Name	TurboHawk® Peripheral Plaque Excision System
510(k) Number	K093301
510(k) Clearance Date	November 6, 2009

4. Device Description

The TurboHawk® Peripheral Plaque Excision System (TurboHawk Catheter and ev3 Cutter Driver) is designed for the treatment of de novo and restenotic calcified and non-calcified atherosclerotic lesions located in native peripheral arteries. When used in complex, hard, calcified lesions, the TurboHawk should be paired with the SpiderFX® Embolic Protection Device to mitigate any risk of distal embolization that may be

generated by the breakdown of heavily calcified plaque. The TurboHawk Catheter consists of a flexible shaft designed to track over a 0.014" guidewire. At the distal end of the TurboHawk Catheter is a small cutting assembly comprised of a rotating inner cutter contained within a tubular housing. The proximal end of the TurboHawk Catheter contains a connector and cutter positioning lever (thumb switch) designed to fit into the ev3 Cutter Driver. The ev3 Cutter Driver is a handheld, disposable, battery-driven unit which powers the system.

The TurboHawk Peripheral Plaque Excision System has two switches: 1) the ev3 Cutter Driver main power switch and 2) the TurboHawk Catheter thumb switch. The ev3 Cutter Driver main power switch supplies power to the device when turned ON. The TurboHawk Catheter thumb switch activates the drive shaft and engages the cutter when pulled proximally to the ON position. With the cutter engaged, the TurboHawk Catheter is slowly advanced across the lesion, shaving occlusive material from the artery. The excised tissue is captured and stored in the tip of the device. The cutting process is completed by advancing the TurboHawk Catheter thumb switch distally deactivating the drive shaft and disengaging the cutter. The TurboHawk Catheter thumb switch is fully advanced distally to the OFF position in order to pack the excised plaque into the tip. This cutting sequence is repeated as necessary to achieve the desired degree of plaque excision.

The TurboHawk Peripheral Plaque Excision System uses the following materials: stainless steel, polyimide, tecothane, pebax, nylon, delrin, PTFE, tungsten carbide, titanium, platinum/iridium, ABS, PVC, silicone, polypropylene and hydrophilic coating.

5. Indications for Use

The TurboHawk® Peripheral Plaque Excision System is intended for use in atherectomy of the peripheral vasculature. The TurboHawk is indicated for use in conjunction with the SpiderFX® Embolic Protection Device in the treatment of severely calcified lesions. The TurboHawk is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.

6. Comparison of Technological Characteristics

The proposed TurboHawk Peripheral Plaque Excision System is the identical device as the currently marketed TurboHawk Peripheral Plaque Excision System (K093301). The proposed and predicate devices share the following technological characteristics:

- Fundamental scientific technology and operating principle
- Design & Dimensions
- Materials
- Manufacturing site and methods
- Sterilization site, method, parameters, and sterility assurance level
- Packaging
- Shelf Life

Additionally, the indications for use, intended use, labeling, and Instructions For Use are similar between the proposed and marketed devices. The difference is including use of an ev3 embolic protection device when used in complex, hard, calcified lesions to mitigate risk of distal embolization that may be generated by the breakdown of heavily calcified plaque. Bench testing, *in-vivo* testing and clinical testing were performed to demonstrate the proposed use of the device with the embolic protection device met pre-determined acceptance criteria.

7. Performance Testing Summary

To demonstrate substantial equivalence of the proposed TurboHawk Peripheral Plaque Excision System to the predicate device, the technological characteristics and performance criteria were evaluated. Using internal Risk Analysis procedures, the following tests were performed:

- Compatibility Tests with Embolic Protection Device
- *In Vivo* Studies

The following tests were performed using the predicate TurboHawk Peripheral Plaque Excision System. Test results met the specified acceptance criteria and were included in K093301:

- Cutter Height
- Cycle and Life
- Carbide Edge Attachment
- Driveshaft Torque Tests
- Tensile tests
- Urge Force
- Trackability
- Spin Percentage
- Embolization
- Cut Mass Per Pass
- Tissue Removal
- Package Integrity
- Sterilization
- Biocompatibility
- Shelf Life

The results from these tests demonstrate that the technological characteristics and performance criteria of the TurboHawk Peripheral Plaque Excision System are comparable to the predicate device and that the TurboHawk Peripheral Plaque Excision System performs in a manner equivalent to the predicate device currently on the market.

8. Clinical Summary

DEFINITIVE Ca^{++} was a prospective, multi-center, non-randomized, single-arm study to evaluate the safety and effectiveness of the SilverHawk/TurboHawk and the SpiderFX embolic protection device for the treatment of moderate to severely calcified peripheral arterial disease in the superficial femoral and/or popliteal arteries. An independent Angiographic Core Laboratory and a Clinical Events Committee (CEC) were employed to ensure unbiased review and classification of events and endpoints. 133 subjects from 17 centers were enrolled. The primary safety and effectiveness endpoints were derived from historical registry data using plaque excision.

The proportion of subjects event-free (per Angiographic Core Laboratory review and CEC adjudication) after 30 days was assessed. The 30-day freedom from MAE rate was 93.1% (122/131). The primary effectiveness endpoint was successful revascularization of the target vessel (defined as less than or equal to 50% residual diameter stenosis following plaque excision), was assessed by the site as well as adjudicated by the angiographic core laboratory. Per angiographic core laboratory assessment, the primary effectiveness criterion ($\leq$ 50% residual diameter stenosis) was achieved in 92.0% (150/163) of lesions. Per site assessment, the primary endpoint success criterion was achieved in 97.0% (162/167) of lesions.

9. Conclusions

Based on the intended use, technological characteristics, safety testing, performance testing, and clinical study results included in this submission, ev3 considers the proposed TurboHawk Peripheral Plaque Excision System to be substantially equivalent to the currently marketed TurboHawk Peripheral Plaque Excision System (K093301).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

OCT 27 2011

ev3, Inc.
c/o Ms. Brenda Johnson
Principal Regulatory Affairs Specialist
3033 Campus Drive
Plymouth, MN 55441

Re: K111723
Trade/Device Name: TurboHawk Peripheral Plaque Excision System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: October 7, 2011
Received: October 11, 2011

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K111723

Device Name: TurboHawk® Peripheral Plaque Excision System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111723